

### **REMARKS/ARGUMENTS**

Claims 1-5, 21 and 22 are pending in this application. Claims 1-5, 21 and 22 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Furthermore, claims 1-3, 5, 21 and 22 have been rejected under 35 U.S.C. §102(b) as being anticipated by Groiso U.S. Patent No. 5,993,476.

First, the Examiner is thanked for the courtesies extended in a telephone interview held April 17, 2009, in which the Office Action was discussed.

During the interview, Applicant's undersigned representative discussed both the §112 rejection and the rejection under 35 U.S.C. §102(b).

With respect to the §112 rejection, it was explained that paragraphs 22-24 with reference to Figs. 3a-3d explained the operation of the invention and provided support for the claims. In particular, Figs. 3a-3d show how a bone fracture is repaired using the clip according to the invention. According to paragraph 22 of the specification, the clip is inserted into the bone holes. Thereafter, as shown in Fig. 3c, space 125 between the elongated bridge sections 115a, 115b is increased along the lines AA as shown in Fig. 3C. This causes the engagement legs to approach one another to cause the bone tissue fragments 305a, 305b to come into contact with one another. If the elongated sections 115a and 115b are over-separated, as explained in paragraph 23, the contact pressure between bone tissue fragments 305a and 305b in an area near the top surfaces 315a, 315b may exceed the contact pressure between the bone tissue fragments 305a, 305b in an area near the bottom surfaces 320a, 320b as shown in Fig. 3c.

This increased pressure at the top may cause the bone tissue fragments 305, 305b to pivot upwardly about contact pivot surface 325 (Fig. 3c), thereby causing engagement legs 105a, 105b of clip 100 to pivot away from one another about distal bridging tips 140a, 140b. This is shown in Fig. 3c. In this manner, the longitudinal axes of the bone tissue fragments 305a, 305b become unaligned and a gap 330, see Fig. 3c, forms between the fragments 305a, 305b. In this case, merely bringing elongated bridge sections 115a, 115b closer together to separate bone tissue fragments 305a, 305b may not help alleviate the problem. See paragraph 23 of the specification.

In order to solve this problem, the present invention, according to paragraph 24,

has the non-linear deformable region shown in Figs. 3b and 3c and also shown at 130 in Fig. 1. In the embodiment shown in Figs. 3a-3d, the non-linear deformable region 130 is a depression. As stated in paragraph 23, merely increasing the space between the elongated bridge sections 115a, 115b will not solve the problem. Accordingly, the clip of the invention is structured so that it receives a force in the direction of the legs, i.e., as claimed, in the first direction. Thus, as described in paragraph 24, to close the gap 330 and to ensure proper setting of bone tissue fragments 305a, 305b, a force such as an upward force, i.e., i.e., in the direction of the legs (first direction), is provided to at least partially linearize the non-linear deformable region 130. This is shown in Fig. 3d where the non-linear deformable region forming the depression shown in Fig. 3c has been substantially straightened as shown in Fig. 3d. In particular, as explained in paragraph 24, while applying the force to the elongated sections 115a, 115b, i.e., the force upwardly as described, withdrawal of clip 100 is prevented by simultaneously applying a force, such as a downward force on the distal bridging tips 140a, 140b. The force applied to the elongated sections 115a, 115b of clip 100 causes at least a partial linearization of non-linear deformable region 130. This causes the proximal insertion tips 135a, 135b, (see Fig. 1 and also see Fig. 3d), to pivot with respect to one another about distal bridging tips 140a, 140b thereby causing the gap 330 to close (as shown in Fig. 3d) between the bottom surfaces 320a, 320b of bone tissue fragments 305a, 305b as shown in Fig. 3d.

Thus, the description of Figs. 3a-3d supports the amendment made in the prior Office Action response that the elongated sections of the clip receive a force in the first direction (i.e., in the direction of the engagement legs) in an area of the non-linear deformable region that causes the proximal insertion tips to pivot.

During the interview, the Examiner agreed that the rejection under 35 U.S.C. §112, first paragraph would be withdrawn in view of this showing.

Applicant's undersigned attorney also discussed the §102 rejection of the claims based upon Dr. Groiso's earlier U.S. Patent No. 5,993,476. Applicant's attorney explained that in the prior clip, the non-linear deformable region does not exist. Thus, the prior art device cannot receive a force in the first direction, i.e., in the direction of the legs to substantially straighten the non-linear deformable region and cause the insertion tips to pivot. In particular,

Applicant's undersigned attorney pointed to the description of the '476 patent with respect to Figs. 16, 17 and 18 contained in column 5, lines 3-17. As explained, the '476 patent only describes applying a force in the direction of the gap 8 as shown in Fig. 16 to change the size of the gap, as shown in Fig. 17. This causes the legs 4 to be drawn together as shown in Figs. 17 to 18. However, the '476 patent only describes causing the tips of the legs to pivot by changing the gap, i.e., by providing a force in a direction perpendicular to the direction of the legs and perpendicular to the direction of the bridge sections that are separated.

There is no teaching or suggestion in the '476 reference of applying a force to the non-linear deformable region of the bridge sections in the first direction, i.e., in the direction of the legs, to substantially straighten the non-linear deformable region to cause the legs to pivot, as claimed. Further, because there is no non-linear deformable region as claimed in the '476 patent, there is no reason or suggestion to apply a force in the first direction.

To further differentiate the invention, it was agreed that the claim would be further amended to recite that the elongated sections of the clip receive a force in the first direction in an area of the non-linear deformable region to substantially straighten the non-linear deformable region and cause the proximal insertion tips to pivot. This is what is described in the specification and shown in Figs. 3c and 3d of the present application.

Applicant's undersigned attorney also discussed with the Examiner Fig. 13 of the Groiso '476 reference. Applicant's undersigned attorney explained that Fig. 13 was directed to a clip which allowed bone fragments of different diameters to be fixed. See column 6, lines 61-67. However, there is no teaching or suggestion in the '476 patent of applying any force in the first direction to the Fig. 13 device having the step in the elongated sections to straighten the elongated sections.

In accordance with the Examiner's suggestion, claim 1 has been amended to positively recite the force received by the elongated sections that enables substantially straightening the non-linear deformable region and causing the insertion tips to pivot.

It is submitted that in view of the amended claims, this application is now in condition for allowance.

Similar amendments have been made to the remaining independent claim 21.

During the interview, it was agreed that if the Examiner believes that further amendments are necessary, the Examiner would contact the undersigned in order to reach acceptable claim language.

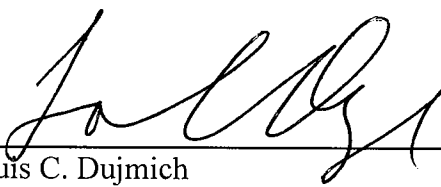
It is believed that a good faith effort has been made to point out the substantial differences between the present invention and the prior art and, in view of this amendment, and the discussion in the interview, summarized herein, that the Examiner should be in a position now to allow this application.

In view of the above, Applicant submits that this application is now in condition for allowance, prompt notification of which is requested.

Respectfully submitted,

THIS CORRESPONDENCE IS BEING  
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